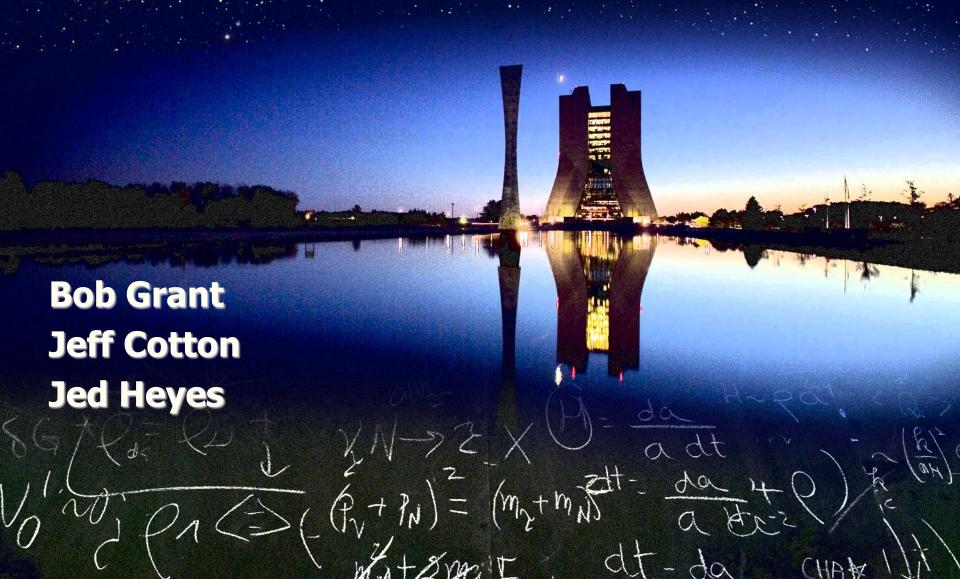
IQA Implementation April 05, 2010



2009 DOE QA Concerns - CAP Status

- ♦ 4 New CAPs OQ-01/04/2010-01 thru -04
 - ❖ C1 & C2 Terms used in CAPA procedure OQ-01/04/2010-01
 - CAPA updated & posted 03/31/10 (complete) Due 04/30/10
 - C3 WSS set maintenance roles OQ-01/04/2010-03
 - WSS / FESHM 1070 updated & posted 01/29/10 (complete) Due 05/31/10
 - ❖ C6 Documentation of acceptance testing varies OQ-01/04/2010-04
 - Inspection assessment added to schedule Due 05/30/10
 - ❖ C7 & C8 Identify assessment criteria, define terms OQ-01/04/2010-02
 - C7 Procedure updated & posted 04/05/10 (complete) Due 05/15/10
 - C8 Manual in process Due 05/15/10



2009 DOE QA Concerns - CAP Status

- Existing As-Is CAPs
 - C5 Fermilab Chief Engineer OQ-05/22/2009-01
 - Elevated to AC and Laboratory Director
 - C4 & SC1 (sig. concern) Inconsistent engineering practices, lack of Engineering Manual - 05/22/2009-02
 - Draft Manual updated, review scheduled with Laboratory Director Due 07/31/10
 - ❖ C9 & C10 S/CI roles & disposition OQ-05/30/2009-06
 - Procedures updated & posted 03/19/2010 (complete) Due 03/19/10



2009 DOE QA Concerns – 4 CAPs from 2006 DOE QA assessment

- Criterion 2 Job specific training OQ-08/10/2009-01
 - System Changed 01/01/10 (complete) Due 01/01/10 ongoing roll out
- Criterion 4 Document management OQ-08/05/2009-01
 - Teamcenter program of work in progress Due 06/01/10
 - Sharepoint program of work in progress Due 06/01/10
- Criterion 4 Records management OQ-08/05/2009-02
 - Approved, rollout in progress 85% completion Due 09/30/10
- Criterion 8 Calibration AD-05/07/2009-03
 - Equipment being identified, policy being drafted Due 11/01/10



As-Is CAP Status Summary

	CAP Summary by Category as of 03/30/10					
	Table 1 - Pivot Table			Table 2 - Sort on Frequency		
	Count of Category			Count of Category		
	Category	Total		Category	Total	% of Total
*	Assessments	4	*	Documents	34	36.96%
*	Documents	34	*	Qualification & Training	13	14.13%
	Inspection / Test	1	*	Records	13	14.13%
	Item Control	1	*	Program	10	10.87%
*	M&TE	8	*	M&TE	8	8.70%
*	PII	1	*	Assessments	4	4.35%
*	Qualification & Traini	13		Work Processes	3	3.26%
*	Records	13		Inspection / Test	1	1.09%
	S/CI	1		Item Control	1	1.09%
	Work Processes	3	*	PII	1	1.09%
	Design	1		S/CI	1	1.09%
*	Requirements Flowdo	1		Design	1	1.09%
	Quality Improvement	1	*	Requirements Flowdown	1	1.09%
*	Program	10		Quality Improvement	1	1.09%
**	Grand Total	92	**	Grand Total	92	100.00%
	* 23 of 102 elevated to OQBP / Assurance Council					
	** Excludes 10 Cancelled CAPs (duplicate, combined, elevation Includes 5 DOE 2006 QA					
	** 83 CAPs formally accepted by Process Owners others in progress (excludes cancelled)					

44 Implemented, 43 Verified Compared to 29 Implemented & 28 Verified 01/03/2010



Project QA Status

- Science / Project QA
 - Project QAE
 - Presentation on QA to project teams
 - Awaiting Director's signature on project QA charge to proceed
 - As-Is baseline completed
 - Reports delivered to process owners for review
 - Minerva, MINOS, Muon Accelerator, D0, Lattice QCD
 - Last two reports in final draft stage with the team before submittal
 - FICAP, ANSI/ASQ Z1.13 to Fermilab QA Guidelines for Scientific Research
 - Team: Tom King (QAE), Bakul Banerjee (CD), Keith Shuh (PPD)
 - Review committee to be assembled by AD for Research
 - Review gaps, recommend & assign CAPs



Assessment Program

- OQBP Assessment program
 - FY2010 Completed Nov-Mar
 - FESS time & materials
 - AD Linac power amp. tube management
 - BSS Wired telecom
 - ES&H Nuclear materials management
 - consolidated ES&H, QA
 - FY2010 Remaining Apr-Sept
 - TD Work Process Controls
 - consolidated tripartite DOE, ES&H, QA
 - CD WAN
 - AD Power outage recovery (leverage RCA from CD outage)



Assessment Program

- OQBP Assessment program
 - FY2011 Being planned (# contingent on resources)
 - Tentative candidates include
 - PPD Requirements management
 - Scientific editorial review (by request)
 - Divisions receipt inspection & test
 - Sections receipt inspection & test
 - EVMS
 - Divisions S/CI implementation
 - Sections S/CI implementation
 - Divisions M&TE
 - Sections M&TE



Accomplishments between last brief and Mar 31, 2010

- General employee QA training
 - Training & test complete, posted, ITNA updates complete
 - Mostly positive feedback
- Automated Graded Approach Tool tested & submitted to production
 - Testing extended due to resource limitations in production environment
- Assessment Manual & Procedures completed
 - Additional review & reconciliation with D/S/Cs
 - Updated for new CAPs from 2009 DOE QA assessment
 - Schedule consolidation began requires extensive coordination
- ♦ S/CI Procedure updates added, comments reconciled, posted
- ♦ FICAP Lessons learned program implemented 1st new LL entered
- ◆ As-Is science report being prepared for research AD & committee



Future Targets Against Schedule

- ♦ Consolidated assessment program June 30, 2010
 - Began before scheduled start
- ♦ Complete acceptance of Corrective Actions from Science As-Is for QA implementation June 30, 2010
- Contractor Assurance
 - ❖ Procedure Due June 21, 2010
 - Management Review
 - Worker Feedback
- Modify FICAP to accommodate H13
 - Targeting October 31st, 2010



Future Targets Against Schedule

Root Cause Analysis Training & Graded Approach S/CI Program

Establish Lessons Learned Program

Build CAPA Procedure

Build Management (Self) Assessment Procedure

Science As-Is

Conduct Assessment

Final Report

CAP Development and Approval

Contractor Assurance

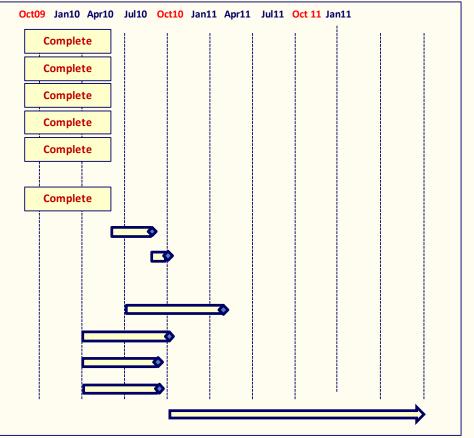
Modify FICAP to Accommodate H13 Clause

Build Consolidated Assessment Program

Complete Management Review Procedure

Complete Worker Feedback Procedure

Continuous Process Improvement





More Discussion Items

- ♦ FSO OQBP Joint Activities
 - Meeting on impact of H13 Clause on QA & CA
 - PEMP
 - Documents (e.g. assessment program)
 - Schedules
 - ❖ Next quarterly DOE QA brief by 15 Jul 2010
 - Next DOE QA assessment (scheduling, criteria, scope etc)



IQA Implementation

Questions?

